DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

947360

November 7, 2003

WARNING LETTER
CHI-1-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Daniel T. Rose, President
Trouw Nutrition USA, LLC
115 Executive Drive,
Highland, IL 62249

Dear Mr. Rose:

An inspection of your headquarters facility at Highland, Illinois, conducted on June 26, 2003, by an investigator of the U. S. Food and Drug Administration (FDA), revealed that your firm had made several shipments of a Category II, Type A Medicated Article, Amprol 25%, to a feed mill which does not hold a valid FDA Medicated Feed Mill License, a violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Pursuant to Section 512(a)(1) of the Act, 21 U.S.C. 360b(a)(1), a new animal drug (in this case, the Category II, Type A medicated article) is deemed unsafe, and therefore, adulterated under Section 501(a)(5), 21 U.S.C. 351(a)(5) if it is removed from a distributor's establishment for use in the manufacture of animal feed, unless at the time of such removal, the distributor has an unrevoked written statement from the consignee of the drug, or notice from the Secretary of Health and Human Services, to the effect that, with respect to the use of such drug in animal feed, such consignee; (i) holds a license and possesses current approved labeling for such drug in animal feed; or (ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of a license. Your firm had no such written statement on file from the feed mill to which you sold the Amprol 25% (amprolium 25%). Accordingly, removal of a Category II, Type A Medicated Article from your facility for the manufacture of feed by the unlicensed feed mill violates Section 512(a)(1) of the Act, causing the new animal drug to be adulterated.

As a distributor of materials intended for animal use, you are responsible for assuring that your overall operation and the products you distribute are in compliance with the law. This includes ensuring that each site where your firm handles Category II, Type A Medicated Articles adheres to the requirement not to ship to unlicensed or unauthorized parties.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

We acknowledge that during our inspection you reported having written procedures to instruct sales people to verify that a written agreement and/or Medicated Feed License (MFL) is on file before shipping a customer Category II, Type A drugs and that you just instituted a computer system upgrade to aid in this MFL verification process. Your firm needs to insure that established effective distribution control procedures are in place to assure that such violations do not recur.

Please advise this office in writing within 15 working days of the receipt of this letter of any further steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step along with documentation as appropriate that demonstrate procedures taken to correct the violation and prevent its recurrence.

Please send your reply to the Food and Drug Administration, Attention: Paul A. Boehmer, Compliance Officer, at the above address. If you have questions regarding any issue in this letter please contact Mr. Boehmer at (312) 596-4217.

Sincerely,

for Gerald Berg
Acting District Director